DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE

SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION

CENTER FOR SUBSTANCE ABUSE TREATMENT
CENTER FOR MENTAL HEALTH SERVICES
CENTER FOR SUBSTANCE ABUSE PREVENTION

COOPERATIVE AGREEMENT TO STUDY WOMEN WITH ALCOHOL, DRUG ABUSE AND MENTAL HEALTH (ADM) DISORDERS WHO HAVE HISTORIES OF VIOLENCE: PHASE II

SHORT TITLE: WOMEN, ADM DISORDERS & VIOLENCE II

Guidance for Applicants (GFA) No. TI 00-003
Part I - Programmatic Guidance

Catalog of Federal Domestic Assistance (CFDA) No. 93.230

Under the authority of Section 501(d)(5) of the Public Health Service Act, as amended (42 USC 290aa), and subject to the availability of funds, the SAMHSA Center for Substance Abuse Treatment will accept applications in response to this Guidance for Applicants for the receipt date of June 13, 2000.

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Part I - PROGRAMMATIC GUIDANCE
Table of Contents

[Note to Applicants: In order to prepare an application, PART II, "General Policies and Procedures Applicable to all SAMHSA Applications for Discretionary Grants and Cooperative Agreements" (February 1999 edition), must be used in conjunction with this document, PART I, "Programmatic Guidance."]

Section I - OVERVIEW

The ACooperative Agreement to Study Women with Alcohol, Drug Abuse, and Mental Health (ADM) Disorders who have Histories of Violence: Phase II,@ seeks to generate and apply empirical knowledge about the development of a comprehensive, integrated services approach, and the effectiveness of this approach for the target population of women with ADM disorders who are/have been the victims of violence. This will be accomplished through a multi-model intervention study with quasi-experimental comparison groups with a common interview protocol at baseline, 6 months, and 12 months.

Purpose

The Substance Abuse and Mental Health Services Administration (SAMHSA) announces the availability of cooperative agreements to support a study on women with alcohol, drug abuse and mental health (ADM) disorders who have histories of violence. This program, hereinafter referred to as "Women, ADM Disorders and Violence II," solicits applications from Phase I grantees for cooperative agreements to conduct Phase II of this study.

Phase II will require full scale implementation of integrated strategies, service intervention models, and outcome evaluations. Phase II cooperative agreements include evaluations of alternative models of delivering and financing integrated service models for women with co-occurring ADM disorders (hereinafter referred to as Aco-occurring disorders@) who have histories of physical and/or sexual abuse. Additionally, a subset study published as a second GFA will include an evaluation of the children of these women who have been affected by these experiences. Please do not address Children=s Subset Study issues in your application for this GFA. This Knowledge Development and Application (KDA) program is a result of a partnership among SAMHSA and its three Centers--the Center for Substance Abuse Treatment (CSAT), the Center for Substance Abuse Prevention (CSAP), and the Center for Mental Health Services (CMHS).

Due to the complexity of the study, Phase II will require substantial programmatic involvement of Federal staff from all three of the SAMHSA Centers. The cooperative agreement mechanism is being used because it allows the Federal Government and/or its representative contractors to provide technical assistance to sites, coordinate the development of evaluation designs, collect and analyze data, participate on the Steering Committee, and convene meetings.

Eligibility

Applications for Phase II grants may be submitted only by current SAMHSA Women, ADM Disorders and Violence Phase I study site grantees. Phase II cooperative agreements are restricted to these specific grantees because their study protocols are in place, thus allowing them to proceed immediately

to the next step of expanding the project=s scope to improve the knowledge base. In addition, Phase I grantees have already: (1) established an integrated system of care for women with co-occurring disorders who have histories of physical and sexual abuse, (2) determined the most promising services intervention models for this population, and (3) developed project protocols in compliance with multi-site requirements established by the steering committee.

Availability of Funds

It is estimated that $7.5 million will be available to support approximately 10 awards for study sites. The amount of an award is expected to range from $700,000 to $750,000 in total costs (direct+ indirect) per fiscal year. Actual funding levels will depend upon the availability of appropriated funds.

Funds may be used to conduct all aspects of data collection and evaluation. A limit of 25 percent of the funds is available for enhancing the comprehensiveness and coordination of existing services necessary to fully implement the proposed study.

Period of Support

Support may be requested for a period of up to three (3) years. Annual awards will be made subject to continued availability of funds and progress achieved.

Section II - PROGRAM DESCRIPTION

Supporting Documentation

Current information reported by SAMHSA underscores a significant disparity in the availability of services for women with co-occurring disorders who have experienced trauma and the demand for such services (SAMHSA, 1995). Knowledge gained from CSAT=s and CSAP=s programs for women and children about the impact of violence, and from the CMHS program exploring the role of physical and sexual abuse in the lives of women with serious mental illness has raised concerns and questions about the complex interaction of trauma, substance abuse, and mental health disorders on women and their children. The history and background for this cooperative agreement program, AWomen, ADM Disorders, and Violence Study,@ was fully described in the March, 1998 GFA No. TI 98-004, Women and Violence.

Target Population

The target population is comprised of women, aged 18 and older, with experience of physical and/or sexual abuse who meet the diagnostic criteria for: (1) DSM-IV Axis I substance-related disorder (excluding caffeine and nicotine-related disorders); and (2) who also meet the criteria for DSM-IV Axis I mental disorder or Axis II personality disorder. Either the substance abuse related disorder or the

mental health/personality disorder shall be current (within the past 30 days) while the other disorder may have occurred within the past five years.

In addition, the woman must have had at least two distinct treatment or service episodes within the mental health, substance abuse, or other systems (e.g., criminal justice) that provide substance abuse/mental health care. Self-help groups, including Alcoholics Anonymous do not meet this criterion.

Program Plan

Goal

The primary goal of this study is the generation and application of empirical knowledge about the development of a comprehensive, integrated services approach, and the effectiveness of this approach for the target population of women. This goal will be accomplished through a multi-model intervention study with quasi-experimental (non-random) comparison groups with a common interview protocol at baseline, 6 months, and 12 months. An integrated services approach is defined as a system in which trauma services are integrated with substance abuse, mental health, and other services. In the context of treatment for co-occurring disorders, women=s experiences of abuse and violence often go unaddressed (Harris, 1992). Furthermore, literature reviews conducted by SAMHSA and its contractors regarding the question of how concomitant trauma, substance abuse and mental illness affect women in their roles as mothers show that this topic is virtually unexplored. Because of these service gaps and shortfalls in the knowledge base, SAMHSA seeks to answer the following questions:

- How effective are models for delivering trauma-informed (see Appendix B: Definitions) integrated services (i.e., systems in which trauma services are integrated with substance abuse, and mental health)?
- Among different interventions/models for delivering trauma-informed integrated services, which ones are most effective [relative to one another as well as to existing substance abuse and/or mental health services (known herein as services as usual)]and for which populations?
- How do different components of integrated services, such as trauma services, co-occurring treatment, consumer/survivor/recovery (C/S/R) involvement, and parenting, affect women=s service utilization, perception of services, and outcomes?
- How does the implementation of different integration strategies affect the strength and nature of service system integration achieved?
- Do parenting interventions with women in the target population lead to better parenting skills and satisfaction?

The objectives of this program are:

- Document and compare models for providing services to women with co-occurring disorders and histories of violence.

- # Identify and measure the relationships between components of the integrated services and document the strategies used to achieve services integration.
- # Measure the effectiveness of these innovative service models as compared to one another and to services as usual on outcomes for 1) clients and 2) participating organizations.
- # Examine specific factors within these integrated service models, such as trauma treatment approaches, C/S/R integration, costs, parenting interventions, and cultural or other sub-group variations and their impact on observed outcomes.
- # Synthesize lessons learned regarding models of services provision, strategies for services integration, innovative accomplishments regarding factors within integrated service models, and summarize local, State, and national public policy impacts that are project-related.

Cooperative Agreement - Roles

The implementation of Phase II of the Women, ADM Disorders and Violence Study will involve the cooperation and collaboration of: (1) the Study Sites, (2) Consumer/Survivor/ Recovering persons (C/S/Rs) at each study site, (3) the Coordinating Center, and (4) Federal staff. Representatives of these four groups will comprise the Women, Co-Occurring Disorders and Violence Steering Committee. The Steering Committee established major subcommittees in Phase I, and may continue to establish new subcommittees and retire others as it strives to accomplish its objectives. The overall program requires all participants to understand their particular roles and to make adjustments in individual goals to achieve the overall success of the program.

Steering Committee: The Steering Committee will be composed of the project director of the Coordinating Center, the project director from each of the study sites, and four additional site representatives (one of whom must be a C/S/R), and SAMHSA staff. The chair of the Steering Committee will be one of the grantees and will be appointed by the CSAT Director. SAMHSA staff may participate as full members of the subcommittees that are formed. The Steering Committee will continue to operate with consensus agreement on most decisions. All decisions which cannot be made by consensus will be made by majority vote. In terms of voting on Steering Committee issues, the votes are tallied as: two votes per site (project director and C/S/R), two votes from SAMHSA, and one vote from the Coordinating Center. SAMHSA retains authority to override decisions made by the Steering Committee that are inconsistent with the goals of the GFA. AEx Officio@ members may be elected jointly by SAMHSA staff, project directors and C/S/Rs. AEx-Officio@ members may not vote.

The first meeting of the Phase II Steering Committee will be convened at the request of SAMHSA within one month of the Phase II awards. It is estimated that at least three meetings will be needed in each of the three years of Phase II. In addition, there may also be up to two meetings for each subcommittee to carry out its tasks. Meetings will be held in the Washington D.C., area. Study site applicants should budget for five participants (travel, lodging, and per diem) per Steering Committee meeting.

All participating study sites must agree to abide by the common protocol study design and policy recommendations developed by the Steering Committee and any required SAMHSA approvals set forth in the terms and conditions of the grant award.

The responsibilities of the Steering Committee subcommittees are set forth in broad terms on pages 29-31 of the March, 1998 GFA No. TI 98-004, Women and Violence, and remain as described.

Consistent with the provisions of 45 CFR 74.36, the Steering Committee will develop policies on data sharing and access to data and materials.

Coordinating Center: One role of the Coordinating Center is to take the lead on cross-site publications. The sites are responsible for their own site-specific publications. Publications will be written and authorship decided using procedures developed by the committee. All participants will be subject to the publication/authorship policies to be developed by the Steering Committee. The quality of publications resulting from the Program will be the responsibility of the authors. (NOTE: Publications on which SAMHSA staff are included as authors or co-authors will receive internal agency clearance.) For a description of the full role of the Coordinating Center refer to pages 27-28 of the March, 1998 GFA No. TI 98-004.

Study Sites: Study Sites must participate in, and cooperate fully with, the Steering Committee, the Coordinating Center, and Federal staff in the implementation and evaluation of their projects. Activities include: (1) compliance with all aspects of the terms and conditions of the cooperative agreement; (2) provision of information necessary for SAMHSA to meet reporting requirements of the Government Performance and Results Act (GPRA); (3) cooperation with the Coordinating Center in accepting guidance and responding to requests for information relevant to the Program; and, (4) cooperation with Federal staff in accepting guidance and responding to requests for information relevant to the Program. In addition, each Study Site project director or evaluator must participate on the Steering Committee and its subcommittees to: (1) refine multi-site questions, hypotheses, and the process and the outcome evaluation protocol; (2) use common interview protocols and other data collection instruments; (3) complete annual Administrative Reporting Form (ARF); (4) adhere to format, content, and timetable for submitting data to the Coordinating Center; (5) collect and transmit the necessary data for the Cost-Finding Study to the Coordinating Center; (6) participate in annual site visits; (7) participate in interviewer training; and (8) participate in workgroups for developing 6 and 12 month follow-up interviews. Finally, study site grantees are expected to take advantage of the technical assistance that will be available from Federal staff and the Coordinating Center in post-award activities.
Because of the importance of understanding issues from a C/S/R perspective, it is required that each study site participate fully in Steering Committee and Coordinating Center recommendations for implementing C/S/R involvement and participation. The basic principle to be followed is that fostering C/S/R integration in all aspects of the project is a crucial element to its success. Because the role of the site-elected C/S/R representative requires that they vote on Steering Committee decisions, the site is expected to provide them with the resources and technical assistance necessary to ensure their full

understanding, participation, and fully informed representation.
Study sites will submit annual non-competing continuation applications during Phase II. In addition, study sites will have regular reporting requirements to the Coordinating Center and SAMHSA. The content and timing of these regular reports will be developed by the Coordinating Center in consultation with the Steering Committee.

Federal Staff: The cooperative agreement mechanism is only used when substantial post-award Federal programmatic participation in the conduct of the Program is required. It is anticipated that the SAMHSA participation in this program will be substantial. The government project officers (GPOs) will monitor the overall progress of the program. SAMHSA=s role will be to:

- # Participate on the Steering Committee, program subcommittees, or other work groups established to facilitate accomplishment of the program goals.
- # Provide guidance on study design requirements.
- # Ensure accountability of study sites and Coordinating Center.
- # Arrange meetings designed to support activities of the individual cooperative agreement awardees.
- # Provide technical assistance in implementing program activities throughout the course of the program.
- # Review and approve each stage of program activities.
- # Conduct site visits to monitor the development and implementation of the programmatic activities and/or engage consultants to advise on programmatic issues and conduct site visits.
- # Provide support services or outside consultants for training, evaluation, and data collection.
- # Provide guidance to enhance the potential replicability of results.
- # Author or co-author publications to disseminate program findings.
- # Provide technical assistance on strategies to enhance the dissemination and application of study findings in States and localities.

Design

Evaluation, including the multi-site process and outcome protocols being developed by the Steering Committee and Coordinating Center in Phase I, is the central component of this GFA. This design consists of a multi-model one year intervention study with quasi-experimental (non-random) comparison groups. A common interview protocol will be used at baseline, 6 and 12 months on the enrolled subjects to compare variations in outcomes across multiple sites. Two conditions will be compared in this design: (1) integrated services (hereafter referred to as the Integrated Condition), the experimental group; and (2) non-integrated or services as usual (hereafter referred to as the Usual Care Condition), the control/comparison group. The operational definition of integrated services was determined by the Steering Committee and is provided in Appendix B: Definitions. Although not necessarily randomly assigned to experimental groups, women for both Conditions must meet the same study eligibility criteria (as described under Target Population) and be clinically, demographically and geographically

comparable. Furthermore, within the two groups, there are two distinct levels of services: (1) organizational/program level and (2) clinical/individual level.

During Phase I, the Steering Committee voted that, for the Integrated Condition, each site must demonstrate that they are operating at or above the third level of service system integration, called Coordination.[1] (see Definitions). Each study site participating in Phase II is required to demonstrate that their Integrated Services condition has at least those service providers and support systems necessary to offer all of the core services as members of the Abroad array of service providers and support systems@ participating in the Coordinated Services. The following core services must be offered in the Integrated Condition (see Appendix B - Definitions).

- Outreach and Engagement
- Screening and Assessment
- Treatment Activities
- Parenting Skills
- Resource Coordination and Advocacy
- Trauma-Specific Services
- Crisis Intervention
- Peer-Run Services

[1] In Konrad, 1996, five levels of integration are described: 1) information sharing and communication, 2) cooperation, 3) coordination, 4) collaboration, and 5) systems integration.